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August 24, 2007

BY HAND DELIVERY

REDACTED

The Honorable Mary Pat Thyng
United States District Court
844 North King Street
Wilmington, DE 19801

Re: Roquette Freres v. SPI Pharma, Inc., et al.
C.A. No. 06-540-***

Dear Magistrate Judge Thyng:

We are counsel for Defendant SPI Pharma, Inc. ("SPI") in the above-referenced patent infringement action and write in advance of the teleconference scheduled before Your Honor next week to address the parties' respective discovery issues. For the following reasons, and for any further reasons offered at the teleconference, SPI respectfully requests that Your Honor order Plaintiff Roquette Freres ("Roquette") to comply with SPI's outstanding discovery requests.

I. Background

Roquette's document production is woefully inadequate. Initially, Roquette produced less than 1,200 pages. Three hundred of those pages comprised various corporate organization charts (which were responsive to only one of SPI's forty-one document requests) and six hundred pages were publicly-available patent file histories. Roquette later supplemented its document production, but, until today, its total production was just over 1,300 pages.¹

In addition, Roquette's responses to SPI's interrogatories are deficient, as in many cases Roquette does not even attempt to provide meaningful responses. For example, in response to SPI's Interrogatory No. 7, Roquette merely states that it "obtained and tested samples of the accused product," although that interrogatory asked for a detailed explanation of such testing. SPI complained about Roquette's interrogatory responses by letter dated June 1, 2007. (Exh. A).

In response to Roquette's contention that its document production and written discovery responses were sufficient, SPI set forth specific deficiencies that required supplementation. (Exh. B).

¹ SPI just received today a supplemental document production from Roquette that totals 600 pages. The bulk of this production appears to be publicly-available, foreign prosecution history files for the patent in suit, although further review of this production is necessary to confirm its contents.

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At SPI's behest, the parties then held a "meet and confer" teleconference on July 9, 2007, and Roquette promised to supplement its initial document production and written discovery responses. (Exh. C). However, despite Roquette's later supplementation, many deficiencies persist. (Exh. D).

In particular, to date Roquette has not produced the following highly relevant information: (i) test protocols and raw data regarding its testing of SPI's Mannogem™ EZ product; (ii) a list of products (and accompanying samples) associated with French patent applications and their U.S. and foreign counterparts relevant to the patent-in-suit; (iii) a narrative explanation of the conception and reduction to practice of the alleged invention of the patent-in-suit, along with complete and detailed lab notebooks; (iv) patent prosecution files of attorneys and foreign agents in connection with the patent-in-suit and foreign counterparts; and (v) evidence concerning secondary indicia of nonobviousness.

II. Argument

(i) Test protocols and raw data for alleged infringement tests

SPI has repeatedly asked for, and Roquette has not objected to, production of this critical information. To date, Roquette has produced a paucity of documents related to alleged infringement testing. Roquette has represented to SPI that it has made a diligent search and has no additional documents related to alleged infringement testing. SPI requests that Your Honor confirm Roquette's representation so that SPI may be assured that Roquette has produced all the documents related to its alleged infringement testing.

(ii) Product list and samples

A list of Roquette's products (and samples of those products) that utilize the alleged invention of Roquette's French '045 and '046 patent applications, and U.S. and foreign counterparts thereto, is relevant to SPI's invalidity defenses and counterclaims. Roquette cited the '045 and '046 French patent applications in the specification of the '777 patent (see '777 patent Col. 2, lns. 29-57; Col. 4, ln. 65 – Col. 5, ln. 7; Col. 5, lns. 45-50; Col. 7, ln. 66 – Col. 8, ln. 3; and Table 1 (Cols. 11 and 12)) and the Patent Examiner repeatedly rejected the '777 patent application based on the U.S. counterpart to the '045 French patent application.

(iii) Conception and reduction to practice of the alleged invention

Information regarding Roquette's conception and reduction to practice is relevant to determinations of obviousness and anticipation, and necessary to substantiate the inventors' sworn claims that they are the first and original inventors of the invention. *See* 35 U.S.C. §§ 102, 103; 28 U.S.C. § 1928; *see also Lamoreux v. Genesis Pharmacy Servs., Inc.*, 226 F.R.D. 154, 160 (D. Conn. 2004) (holding that dates regarding conception and reduction to practice are "incontrovertibly relevant to defenses and counterclaims based upon statutes which turn almost exclusively on such dates."); *McKesson Info. Solutions LLC v. Epic Sys. Corp.*, No. 1:06-CV-

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2965-JTC, 2007 U.S. Dist. LEXIS 48185, at *5 (N.D. Ga. June 26, 2007) (stating that the Federal Rules of Civil Procedure “contemplate that a party receive this information up front, during discovery, so that when the time comes to discharge its burden it has the ammunition necessary to do so.”). The documents referred to by Roquette in its interrogatory response related to this issue do not adequately supply the requested information. (Exh. D, p. 2). SPI is entitled to a narrative response that sets forth Roquette’s conception and reduction to practice of the alleged invention. To the extent necessary, SPI requests that it be permitted to inspect Roquette’s original laboratory notebooks on an “Outside Counsel Eyes Only” basis to confirm this information.

(iv) Patent prosecution files

The patent prosecution files of Roquette’s attorneys and foreign agents in connection with the ‘777 patent and foreign counterparts are relevant because they “could lead potentially to admissible evidence concerning what a person of ordinary skill in the art would have understood ambiguous terms in prior art references to mean or to evidence that could impeach [Roquette] insofar as it contends that the invention disclosed in the [‘777] patent is novel.” *Innogenetics, N.V. v. Abbott Labs.*, 2006 U.S. Dist. LEXIS 57560, at *4-5 (W.D. Wis. Aug. 14, 2006). Additionally, the documents could lead SPI to further invalidating prior art references. *Id.* at *5. Such reasons have been found to be entirely sufficient to compel production of the U.S. and foreign prosecution files pursuant to Fed. R. Civ. P. 26. *Id.* at *5-6. *See also Golden Trade, S.r.L. v. Lee Apparel Co.*, 143, F.R.D. 514, 524-526 (S.D.N.Y. 1992) (ordering plaintiff to produce foreign agents’ prosecution files in its “possession, custody or control”).

(v) Secondary indicia evidence

Evidence concerning secondary indicia of nonobviousness is relevant to SPI invalidity defenses and counterclaims, and is discoverable under Fed. R. Civ. P. 26. *See also Applied Biosystems, Inc. v. Cruachem, Inc.*, 1990 U.S. Dist LEXIS 21003, at *8 (D. Del. Aug. 3, 1990) (compelling production of documents relevant to secondary indicia of nonobviousness); *Mixing Equip. Co., Inc. v. Innova-Tech, Inc.*, 1986 U.S. Dist. LEXIS 21134, at *3-6 (E.D. Pa. Aug. 27, 1986) (ordering supplementation of interrogatory responses relevant to commercial success); *Sun Elec. Corp. v. The Allen Group, Inc.*, 1985 U.S. Dist. LEXIS 22571, *9-10 (N.D. Ill. Feb. 14, 1985) (compelling production of documents and supplementation of interrogatory responses relevant to commercial success). Roquette has promised to produce such information, but has failed to do so. (Exh. E., p. 3).

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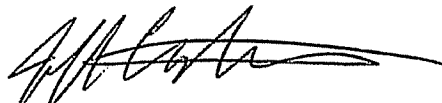
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SPI respectfully asks the Court to compel Roquette to redress its discovery failures and immediately produce documents and samples, and supplement its interrogatory responses, in fulfillment of SPI's outstanding requests.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Jeff Castellano', with a long horizontal flourish extending to the right.

Jeffrey T. Castellano (I.D. No. 4837)

JTC:mmeeh

Attachments

cc: Clerk, U.S. District Court (By Hand Delivery)
Mary B. Graham, Esquire (By Hand Delivery)
Julia Heaney, Esquire (By Hand Delivery)
Douglas V. Rigler, Esquire (By E-mail)

EXHIBIT A

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Oren D. Langer
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June 1, 2007

VIA E-MAIL AND FIRST CLASS MAIL

Douglas V. Rigler, Esq.
Young & Thompson
745 South 23rd Street
Arlington, Virginia 22202

Re: *Roquette Freres v. SPI Pharma, Inc. and Drytec Ltd.*, Civ. No. 06-540 (***)
Client-Matter No. 059717-3025

Dear Douglas:

We have reviewed Roquette's document production, received on May 25, 2007, and find it seriously deficient. Given Roquette's request for a 30-day extension to produce responsive documents, and the four additional days for Roquette finally to send the documents, it is unacceptable that your entire production totals less than 1,200 pages, not even enough to fill half a bankers' box. Of those 1,200 pages, the first 300 are corporate organization charts and the last 600 are publicly available patent file histories. In contrast, SPI Pharma has produced over 9,000 pages of documents, more than **seven times** the size of Roquette's production.

We find it hard to believe that Roquette's production to date constitutes all the responsive documents to our requests. For example, there are very few, if any, documents relating or referring to Roquette's conception and reduction to practice of the '777 patent, including research and testing of the alleged invention, and the same applies for documents relating or referring to testing of SPI Pharma's Mannogem™ EZ product. We therefore demand that Roquette immediately supplement its production. If Roquette is withholding any responsive documents on the basis of privilege, Roquette must immediately produce a log of privileged documents pursuant to the discovery rules. Also, please explain the gaps in Roquette's production, e.g., we are missing documents bearing production numbers RF000438 and RF000479-480.

Morgan Lewis
C O U N S E L O R S A T L A W

Douglas V. Rigler, Esq.
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We note also that many of Roquette's responses to SPI Pharma's Interrogatories are unsatisfactory, in many instances not even attempting to provide answers. Specifically, we demand that Roquette immediately supplement its responses to Interrogatory Nos. 2, 5, 7, 8, 9, 11, 12, 13 and 14 and provide the information requested therein.

We expect Roquette's prompt supplementation of its document production and interrogatory responses or at least no later than June 15, 2007. I look forward to your reply.

Sincerely,

A handwritten signature in black ink, appearing to read 'Oren D. Langer', enclosed within a large, loopy oval shape.

Oren D. Langer

c: Jeffrey R. Snay, Esq. (via email)
Brian P. Murphy, Esq. (via email)
John W. Shaw, Esq. (via email)

EXHIBIT B

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June 27, 2007

VIA E-MAIL AND FIRST CLASS MAIL

Jeffrey R. Snay, Esq.
Young & Thompson
745 South 23rd Street
Arlington, Virginia 22202

Re: *Roquette Freres v. SPI Pharma, Inc. and Drytec Ltd.*, Civ. No. 06-540 (***)
Client-Matter No. 059717-3025

Dear Jeffrey:

This is further to your June 18 letter, which replied to our letters of June 1 and 15.

We frankly find incredible your assertion that the 1,200 pages produced on May 25 constitutes Roquette's entire document production in this case and that "there are no additional documents to be produced." For example, Roquette has not produced any laboratory notebooks, reports or other documents showing its test methods and protocols used in the alleged testing of the accused product nor the raw data of the test results. We do not believe that the scientists who allegedly tested the accused Mannogem™ EZ product kept no records of their tests, materials and methods.

Below we set forth the specific deficiencies in Roquette's document production and written discovery responses. To the extent Roquette asserts that it has already produced responsive documents to the requests below, we request an immediate identification of them by their Bates-numbered pages. Alternatively, if Roquette is withholding documents based on privilege that would otherwise be responsive to those requests, we request that you immediately provide us with a Privilege Log that identifies those documents.

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June 27, 2007
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Interrogatories

Roquette promised to supplement certain of its interrogatory responses by today, but we have not as yet received them. Roquette's responses to date are inadequate and we demand supplementation as follows:

Interrogatory No. 2 and 7:

In response to these interrogatories, Roquette states that "Roquette obtained and tested samples of SPI's spray-dried mannitol product" and determined those samples to be within the product claims of the patent-in-suit. At this stage of the litigation, Roquette must specifically describe all of the evidence supporting its allegation of infringement, including the tests of the accused product that Roquette relied upon as grounds to bring suit. Conclusory and vague statements such as the ones used to answer these interrogatories, i.e., "obtained and tested," are not sufficiently specific and detailed as required by Fed. R. Civ. P. 33. Roquette must identify each and every product tested for alleged infringement, describe that testing in detail and with specificity and produce all related documents and things

Interrogatory No. 9:

Evidence of conception and reduction to practice is highly relevant to SPI Pharma's defenses under 35 U.S.C. §§ 101, 102, 103 and 112, and Roquette's contrary assertion is baseless. Roquette must set forth, in narrative form, information that includes, but is not limited to, the name(s) of the individual(s) who conceived the invention and reduced it to practice, when conception and reduction to practice occurred, where conception and reduction to practice occurred and under what circumstances, etc. Moreover, Roquette must identify all supporting documents, notebooks, internal memoranda, etc. by Bates number that support the facts of conception and reduction to practice.

Interrogatory No. 11:

Roquette's response to Interrogatory No. 11 merely notes that Pearlitol® SD 200 is covered by one or more claims of the patent-in-suit. Roquette must specifically explain how each claim of the patent-in-suit covers their Pearlitol® SD 200 product. This information is relevant to issues of claim construction, infringement and damages and SPI Pharma is entitled to a detailed response.

Interrogatory No. 12:

Roquette did not "identif[y] all tests and analyses performed for the purposes of determining whether or not the product/process infringes the patent-in-suit, and identif[y] all documents and things relating to the foregoing." Roquette merely states that "an analysis of the sample was

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completed...with the conclusion that the sample infringed.” That response is completely inadequate under Fed. R. Civ. P. 33 and must be immediately supplemented.

Interrogatory No. 13:

Roquette’s refuses to answer this interrogatory because it contends that “SPI has not asserted with specificity any basis of its claims of unenforceability due to laches or equitable estoppel.” On the contrary, SPI Pharma’s responses to Roquette’s Interrogatory Nos. 9 and 10 provide a specific account of the factual and legal bases for SPI Pharma’s contention that the patent-in-suit is unenforceable under the doctrines of laches and/or equitable estoppel. Roquette must immediately provide a full and complete response to this interrogatory.

Document Requests

SPI Pharma served Roquette with SPI Pharma’s First Set of Requests for the Production of Documents and Things on March 19, 2007. It is now more than three months later and Roquette has failed to address the following deficiencies in its written responses and document production:

Request No. 1:

Roquette’s production is deficient. SPI’s document request seeks each and every patent and application, copies of the prosecution history, documents and things provided to the prosecuting attorney(s) or agent(s), documents and things furnished to the U.S. Patent Examiner or analogous foreign authority, and documents and things relating to any interviews with the U.S. Patent Examiner or analogous foreign authority associated with the patent-in-suit and any of its foreign counterparts. Although Roquette agreed to produce responsive documents, Roquette’s production to-date is incomplete and requires immediate supplementation. In particular, Roquette has failed to produce any prosecution files of attorneys or foreign agents either in Roquette’s possession or in the possession of said attorneys or foreign agents. These documents are highly relevant and we demand their immediate production. If Roquette asserts that it has already produced responsive documents to this request, we demand that you immediately identify them by bates page.

Request Nos. 2, 3, 23, 24, 25:

Roquette’s objections to these requests and blanket refusal to produce responsive documents are meritless. These documents are clearly relevant to SPI Pharma’s noninfringement and invalidity defenses and counterclaims. In particular, Document Request Nos. 2 and 3 pertain to documents related to the subject matter of the patent-in-suit and its foreign counterparts. Document Request Nos. 23-25 all pertain to secondary indicia of non-obviousness, which is highly relevant to SPI Pharma’s invalidity defense and counterclaim. If Roquette asserts that it has already produced

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responsive documents to this request, we demand that you immediately identify them by bates page.

Request Nos. 6, 9, 11, 26:

These requests seek: (i) documents supporting Roquette's averments in its Amended Complaint that SPI Pharma is and has been allegedly infringing, and inducing others to allegedly infringe the patent-in-suit (Doc. Req. 6); (ii) documents evidencing testing, experimentation, research test methods or development conducted by Roquette on SPI Pharma's Mannogem™ EZ product (Doc. Req. 9); (iii) documents evidencing testing, experimentation, research test methods or development conducted by Roquette on the subject matter of the patent-in-suit (Doc. Req. No. 11); and (iv) documents and things evidencing any allegations made by Roquette that anyone has infringed the claims of the patent-in-suit (Doc. Req. No. 26). There are no documents in Roquette's production showing the test methodologies, protocols and raw data of the test results in the testing of the accused product that allegedly supports Roquette's claim of patent infringement. The lab notebooks produced merely contain tables of contents referencing dates and general summaries of the experiments that were allegedly conducted on those dates, but none illustrate actual test methods and experimentation protocols used to analyze either Roquette's patented invention or SPI Pharma's accused product. (See RF 00502-9, 00534-85). Similarly, Roquette internal memoranda are wholly devoid of any mention of specific test methodologies used by Roquette scientists that allegedly support Roquette's infringement allegations. (See RF 00352, 00372-78, 00419-37, 00499, 00523-32). If Roquette asserts that it has already produced responsive documents to this request, we demand that you immediately identify them by bates page.

Request No. 4:

This request seeks Roquette's invention development documents with respect to the '777 patent. While Roquette agreed to produce "documents describing, evidencing or constituting: invention disclosures and written descriptions; conception or reduction to practice; individual first disclosure documents; corroboration documents; notebooks; or other records of the work" in response to Document Request No. 4, Roquette has produced very few, if any, responsive documents. Information concerning the conception and reduction to practice of each invention claimed in the patent-in-suit is highly relevant to defenses under 35 U.S.C. §§ 101, 102, 103 and 112. If Roquette asserts that it has already produced responsive documents to this request, we demand that you immediately identify them by bates page.

Request No. 13, 14, 22:

These requests relate generally to Roquette's compliance with the marking or notice provision under 35 U.S.C. § 287. Document Request No. 14 seeks documents evidencing the strength, coverage, legal significance or business significance of the patent-in-suit. Document Request

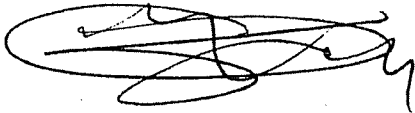
Morgan Lewis
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No. 22 seeks documents concerning any advantage and/or disadvantage of using any product/process either described in or claimed by the patent-in-suit *vis-à-vis* any other product/process. Roquette has produced very few, if any, documents responsive to these requests. Roquette must immediately supplement its production and identify specifically any responsive documents in its production by bates page.

Because we can no longer accept any further delay in resolving these issues, we request that the parties hold a meet and confer telephone conference pursuant to the Judge's rules. We are available on either June 28 or 29 at a time convenient for you. Please let us know which of these dates is preferable, and the time that you would like to conduct the call. We look forward to your prompt reply.

Very truly yours,

A handwritten signature in black ink, appearing to read "Oren D. Langer", enclosed within a hand-drawn oval.

Oren D. Langer

c: Douglas V. Rigler, Esq. (via email)
Brian P. Murphy, Esq. (via email)
John W. Shaw, Esq. (via email)

EXHIBIT C

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July 12, 2007

VIA E-MAIL AND FEDERAL EXPRESS

Douglas V. Rigler, Esq.
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745 South 23rd Street
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Re: *Roquette Freres v. SPI Pharma, Inc. and Drytec Ltd.*, Civ. No. 06-540 (***)
Client-Matter No. 059717-3025

Dear Douglas and Jeffrey:

I write further to the "Meet & Confer" teleconference held by the parties on July 9, 2007, which SPI Pharma had requested to discuss deficiencies in Roquette's document production and written discovery responses.

The following identifies the issues discussed by counsel, the parties' positions, and any measures agreed upon to resolve the issues. We also renew any requests objected to by Roquette and provide reasons why we believe Roquette should reconsider its position.

1. Roquette's Testing of the Accused Product

SPI Pharma expressed its concern that Roquette has not produced any information to date concerning test methodologies, protocols and raw data in connection with Roquette's testing of the accused product. Roquette responded that it has no objection to providing such information and documentation to the extent it exists. Roquette further stated that while it believes its initial search for such information was diligently conducted, a second search has uncovered, *inter alia*, "notes" taken during the course of testing SPI Pharma's accused product witnessed by a French quasi-judicial Magistrate. Roquette promised to produce these notes and other documents by the end of the week. To explain the paucity of documents, Roquette indicated that testing

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documents may no longer exist and/or some of the experiments may have been communicated orally. Roquette stated that it was not withholding documents based on privilege or otherwise, and that SPI Pharma was entitled to this information.

2. '777 Patent - Conception and Reduction to Practice

SPI Pharma asked Roquette to supplement its document production in response to Document Request No. 4 and provide a narrative response to Interrogatory No. 9. SPI Pharma seeks, among other things, the identity of all the individuals who conceived the '777 patented invention and reduced it to practice, the dates of conception and reduction to practice, and the location where conception and reduction to practice occurred. SPI Pharma's position is that such information is highly relevant to its defense and counterclaims of invalidity under 35 U.S.C. §§ 102 and 103.

For example, information regarding conception and reduction to practice is relevant in order to determine, among other things, whether the "invention was known or used by others...before the invention thereof by the applicant" and/or whether the claimed subject matter "would have been obvious at the time the invention was made..." 35 U.S.C. §§ 102 and 103. In addition, the dates for conception and reduction to practice are relevant to substantiate the inventors' claim, under oath, that they are the first and original inventors of the invention. *See* 28 U.S.C. § 1928. *See also Lamoureux v. Genesis Pharmacy Services, Inc.*, 226 F.R.D. 154, 160 (D. Conn. 2004) ("The dates in question – when the plaintiffs conceived and reduced to practice the invention claimed with regard to the 760 Patent – are incontrovertibly relevant to defenses and counterclaims based upon statutes which turn almost exclusively on such dates."); *Mckesson Information Solutions LLC v. Epic Systems Corp.*, 2007 U.S. Dist. LEXIS 48185, *5 (N.D. Ga. June 26, 2007) (The federal rules contemplate that a party receive information related to conception and reduction to practice "during discovery, so that when the time comes to discharge its burden it has the ammunition necessary to do so.").

Although disputing relevancy of this information and responding that it had provided SPI Pharma with the constructive date of conception and reduction to practice by virtue of the patent filing date, Roquette did indicate that it would reconsider supplementing its discovery responses to SPI Pharma's Document Request No. 4 and Interrogatory No. 9.

Based on the reasons and case law outlined above, SPI Pharma renews its request for this information.

Douglas V. Rigler, Esq.
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3. '777 Patent And Roquette's Products

SPI Pharma reiterated its request for Roquette to supplement its response to Interrogatory No. 11 and explain how each claim of the '777 patent covers Roquette's commercial products. Roquette responded that it will serve a supplemental response by the end of this week.

SPI Pharma also reiterated its request for Roquette to identify and provide samples of all of its products covered by the '777 patent, and Roquette's French '045 and '046 patent applications. This information is relevant to SPI Pharma's invalidity defenses and counterclaims.

For example, Roquette cited the '045 and '046 French patent applications in the specification of the '777 patent (see '777 patent Col. 2, Ins. 29-57; Col. 4, ln. 65 – Col. 5, ln. 7; Col. 5, Ins. 45-50; Col. 7, ln. 66 – Col. 8, ln. 3; and Table 1 (Cols. 11 and 12)) and the Patent Examiner based rejections of the '777 patent application on the U.S. counterparts to the '045 and '046 French patent applications. Roquette produced the file histories of the '045 and '046 French patent applications in their document production to SPI Pharma. It is evident that Roquette believes the subject matter of these two French patent applications is relevant to the issues in this case. Likewise, samples and names of products covered by them, and their U.S. counterparts, are also relevant, particularly to alleged novelty of the '777 patent.

Roquette responded that five (5) samples of the product covered by the '777 patent will be produced to SPI Pharma by the end of this week. Roquette stated, however, that it will not supplement its responses to SPI Pharma Interrogatory Nos. 15-17 and Document Requests Nos. 42-44. Roquette will not identify its products covered by any Roquette patent, U.S. or foreign, other than the '777 patent, or provide samples of any product covered by any Roquette patent, U.S. or foreign, other than the '777 patent.

Based on the reasons outlined above, SPI Pharma renews its request for this information.

4. '777 Patent - U.S. and Foreign Prosecution History Files

SPI Pharma reiterated its request for information under Document Request No. 1, viz., each and every patent and application, copies of the prosecution history, documents and thing provided to the prosecuting attorney(s) or agent(s) and prosecution files of attorneys or foreign agents associated with the '777 patent and its foreign counterparts. Prosecution files associated with the patent-in-suit and its foreign counterparts are relevant to SPI Pharma's arguments concerning claim construction, noninfringement and invalidity.

For example, these documents "could lead potentially to admissible evidence concerning what a person of ordinary skill in the art would have understood ambiguous terms in prior art references to mean or to evidence that could impeach [Roquette] insofar as it contends that the invention

Douglas V. Rigler, Esq.
Jeffrey R. Snay, Esq.
July 12, 2007
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disclosed in the ['777] patent is novel.” *Innogenetics, N.V. v. Abbott Labs.*, 2006 U.S. Dist. LEXIS 57560, *4-*5 (W.D. Wis. Aug. 14, 2006). Additionally, the documents could lead SPI Pharma to further invalidating prior art references that it has not yet discovered. *Id.* at *5. Such reasons have been found to be entirely sufficient to compel production of the U.S. and foreign prosecution files pursuant to Fed. R. Civ. P. 26. *Id.* at *5-*6. See also *Golden Trade, S.r.L. v. Lee Apparel Co.*, 143, F.R.D. 514, 524-526 (S.D.N.Y. 1992) (Court orders plaintiff to produce foreign agents’ prosecution files in its “possession, custody or control”).

Roquette agreed to produce all public foreign counterpart file histories, but asserted that SPI Pharma was not entitled to non-privileged prosecution files from its attorney or agent related to the ‘777 patent and its foreign counterparts. Roquette admitted that it has control over these files, but that it was not going to produce them. Roquette characterized SPI Pharma's request as “make-work” and burdensome.

Based on the reasons and case law outlined above, SPI Pharma renews its request for this information.

5. ‘777 Patent and Any Secondary Indicia Evidence

SPI Pharma reiterated its request that Roquette produce documents related to the subject matter of the ‘777 patent and secondary indicia of non-obviousness. Roquette responded that it will not produce any such documents without SPI Pharma first setting forth its factual allegations supporting its defense and counterclaim of invalidity. While SPI Pharma stated its intention to supplement its responses to Roquette’s contention interrogatories, SPI Pharma disagreed that any supplementation must precede Roquette’s production of responsive documents.

It is indisputable that evidence concerning secondary indicia of nonobviousness is relevant to SPI Pharma’s noninfringement and invalidity defenses and counterclaims. Moreover, nothing in the federal rules supports the *quid pro quo* strategy proffered by Roquette. To the extent Roquette has information and/or documentation related to its rebuttal case, such information is discoverable and SPI Pharma is entitled to it under Fed. R. Civ. P. 26. Additionally, case law is clear that evidence of secondary indicia is discoverable and its production mandated. See *Applied Biosystems, Inc. v. Cruachem, Inc.*, 1990 U.S. Dist LEXIS 21003, *8 (D. Del. Aug. 3, 1990) (Court compels production of documents relevant to secondary indicia of nonobviousness); *Mixing Equipment Co., Inc. v. Innova-Tech, Inc.*, 1986 U.S. Dist. LEXIS 21134, *3-*6 (E.D. Pa. Aug. 27, 1986) (Court orders supplementation of interrogatory responses relevant to the issues of commercial success); *Sun Electric Corp. v. The Allen Group, Inc.*, 1985 U.S. Dist. LEXIS 22571, *9-*10 (N.D. Ill. Feb. 14, 1985) (Court compels production of documents and supplementation of interrogatory responses relevant to the issue of commercial success).

Morgan Lewis
C O U N S E L O R S A T L A W

Douglas V. Rigler, Esq.
Jeffrey R. Snay, Esq.
July 12, 2007
Page 5

Based on the reasons and case law outlined above, SPI Pharma renews its request for this information.

6. Privilege Logs

The parties agreed to exchange privilege logs in the near future. Roquette requested a "cut-off" date for disclosure and suggested August 31, 2006 - *i.e.*, the date of Roquette's filing of the initial complaint in this litigation. SPI Pharma was generally agreeable to using a cut-off date but stated that it wanted to consider a later date than August 31, 2006, particularly in view of the fact that Roquette did not provide notice of its '777 patent until late 2006/early 2007 and Roquette's filing of the First and Second Amended Complaints.

7. Kennet Deposition

Roquette raised concerns about SPI Pharma's objections to the Schedule A document requests attached to Mr. Kennet's deposition notice. Specifically, Roquette requested that SPI Pharma confirm that all the newly joined parties named in the Second Amended Complaint ("Co-Defendants") will produce responsive documents. Roquette requested that we contact Mr. Kennet directly and confirm that he made a diligent search for responsive documents from the files of both Drytec Contract Processing, Ltd. and Anhydro U.K. Ltd. Immediately after the Meet & Confer teleconference, counsel for Co-Defendants contacted Mr. Kennet and advised him accordingly.

We look forward to receiving Roquette's supplemental discovery responses and document production this week, as well as responses to our renewed discovery requests. We will contact you soon to coordinate the parties' service of privilege logs.

Sincerely,

A handwritten signature in black ink, appearing to read "Oren D. Langer", with a stylized flourish at the end.

Oren D. Langer

Enclosure

c: Julia Heaney, Esq. (via e-mail)
John W. Shaw, Esq. (via e-mail)

EXHIBIT D

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Morgan Lewis
C O U N S E L O R S A T L A W

Oren D. Langer
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July 30, 2007

REDACTED

VIA E-MAIL AND FEDERAL EXPRESS

Jeffrey R. Snay, Esq.
Young & Thompson
745 South 23rd Street
Arlington, Virginia 22202

Re: *Roquette Freres v. SPI Pharma, Inc. and Drytec Ltd.*, Civ. No. 06-540 (***)
Client-Matter No. 059717-3025

Dear Jeffrey:

I write in response to your letter dated July 20 concerning our July 9 "Meet & Confer" teleconference.

Roquette's Testing of the Accused Product

We confirm that Roquette has no objection to producing documents related to its testing of the accused Mannogem™ EZ product, including test methodologies, protocols and raw data. Notwithstanding, your production to date is devoid of this information.¹ SPI Pharma, therefore, requests that Roquette specifically identify all documents produced that relate or refer to Roquette's testing of SPI Pharma's accused Mannogem™ EZ product, or otherwise confirm that this information is not in its possession, custody or control. Accordingly, SPI Pharma further

¹ Roquette's production consists of various reports (RF 00372-376, RF 00428-37), emails (RF 00349-50, RF 00353) and memoranda (RF 00352, RF 00377-78) explicitly stating that Roquette tested the accused product. Roquette has admitted to testing SPI Pharma's Mannogem™ EZ product in its interrogatory responses, but no test methodologies, protocols or raw data have been produced associated with these tests.

Morgan Lewis
COUNSELORS AT LAW

Jeffrey R. Snay, Esq.
July 30, 2007
Page 2

requests the earliest possible opportunity to make a personal inspection and any necessary copying at your offices of the original documents associated with Roquette's testing of the accused product. We agree that this inspection will be conducted on an "Outside Counsel Eyes Only" basis. Please let us have a date certain when these original documents will be made available for our inspection and copying at the earliest possible opportunity.

To the extent that Roquette is withholding on the basis of privilege any information related to testing, test methodologies, protocols and raw data, we expect to see that information properly identified on Roquette's privilege log. In this regard, SPI Pharma proposes that the parties exchange privilege logs this week on August 3rd. SPI Pharma is amenable to your earlier suggestion that the parties impose a cut-off date of August 31, 2006 for disclosure on their respective privilege logs.

'777 Patent – Conception and Reduction to Practice

For the reasons stated in my July 12 letter, SPI Pharma is entitled to a supplemental interrogatory response that provides a narrative explanation of the actual events of the conception and reduction to practice of the '777 patent's claimed invention. While Roquette has indicated that it will supplement its interrogatory response to reflect the information related in its July 20 letter, SPI Pharma insists that it is entitled to a detailed explanation of the events related to the '777 patented invention's conception and reduction to practice as relevant to defenses under 35 U.S.C. §§ 101, 102, 103 and 112.

The invention development laboratory notebook pages produced by Roquette lack necessary context and, standing alone, are woefully incomplete.

REDACTED

However, no test methodologies, protocols or raw data are provided for this experiment, or any other experiment, anywhere in any of the pages that Roquette produced.

REDACTED

Accordingly, SPI Pharma requests the earliest possible opportunity to make a personal inspection and any necessary copying at your offices of the original laboratory notebooks that contain the produced pages referenced above. We agree that this inspection will be conducted on an

Jeffrey R. Snay, Esq.
July 30, 2007
Page 3

“Outside Counsel Eyes Only” basis. Please let us have a date certain when these notebooks will be made available for our inspection and copying at the earliest possible opportunity.

‘777 Patent and Roquette’s Products

SPI Pharma disagrees with Roquette’s assertion that the identification of products and samples related to the ‘045 and ‘046 French patent applications is irrelevant. To say that the “sole overlap of the ‘045 and ‘046 French applications with U.S. Patent No. 5,573,777 is that they each share one common inventor...and a common owner...” is demonstrably untrue. The ‘045 and ‘046 references are cited throughout the specification of the patent-in-suit (see ‘777 patent Col. 2, lns. 29-57; Col. 4, ln. 65 – Col. 5, ln. 7; Col. 5, lns. 45-50; Col. 7, ln. 66 – Col. 8, ln. 3; and Table 1 (Cols. 11 and 12)) and the U.S. counterpart of the ‘045 application, U.S. Patent No. 4,661,647, served as the basis for multiple rejections of the ‘777 patent application by the Patent Examiner during its prosecution. For these reasons, and the reasons set forth in my July 12 letter, SPI Pharma demands an identification of the products and production of samples of those products associated with the invention disclosed in the ‘045 and ‘046 French patent applications and its counterparts.

‘777 Patent – U.S. and Foreign Prosecution History Files

SPI Pharma acknowledges that Roquette may need some additional time to collect these documents, but we are now beyond the halfway point in the discovery period. Please produce these documents no later than two weeks from the date of this letter.

Privilege Logs

As noted above, SPI Pharma agreed to the Aug. 31, 2006 cut-off date discussed during our Meet & Confer teleconference. SPI Pharma is prepared to exchange privilege logs on Friday, Aug. 3, 2007 via e-mail at 5:00 PM with a confirmation copy to be sent via federal express. Please advise if this is agreeable to Roquette.

Kennet Deposition

We produced last week

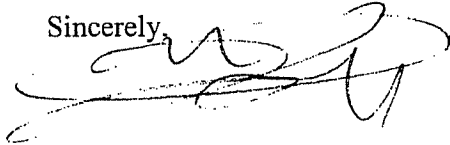
REDACTED

To the extent any additional relevant documents exist, we will produce them to you without delay after receipt from Mr. Kennet. Just for the record, all of the documents related to (ii) were already provided to Roquette in SPI Pharma’s production dated July 9, 2007.

Morgan Lewis
C O U N S E L O R S A T L A W

Jeffrey R. Snay, Esq.
July 30, 2007
Page 4

Sincerely,

A handwritten signature in black ink, appearing to read "Oren D. Langer", written over a horizontal line.

Oren D. Langer

EXHIBIT E

YOUNG & THOMPSON

International Patent & Trademark Law

Established 1903

Emil Bönnelycke
1875-1936

William H. Young
1902-1958

Irvin S. Thompson
1903-1979



July 20, 2007

Oren D. Langer
Morgan, Lewis & Bockius LLP
101 Park Avenue
New York, NY 10178-0060

Via Electronic Mail and Federal Express

Re: *Roquette Freres v. SPI Pharma, Inc.*, C.A. No. 06-540 (***)
Our Ref. 0600-269

Dear Oren,

This responds to your letter of July 12, regarding the teleconference held by the parties on July 9, 2007.

Your letter presents seven topics discussed during the July 9th teleconference. We address each in turn.

1. Roquette's Testing of the Accused Product

We reiterate that Roquette has no objection to providing non-privileged information related to Roquette's testing of accused products, including test methodologies, protocols and raw data. To the extent such information has been located after diligent search, it has been produced.

2. '777 Patent – Conception and Reduction to Practice

Roquette has already identified the individuals responsible for the conception and reduction to practice of the invention claimed in the '777 patent, and has already produced its documents related thereto (including, e.g., RF 00479-578), from which documents the dates of conception and reduction to practice can be derived or ascertained.

Moreover, the '777 patent is entitled to a constructive reduction to practice at least as early as its U.S. filing date. The '777 patent is also entitled to the benefit of its earlier French priority application. That information is plainly evident from the face of the patent.

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Oren D. Langer
July 20, 2007
Page 2 of 4

Roquette intends to supplement its interrogatory responses to reflect the foregoing information, and agrees to do so next week.

3. **'777 Patent and Roquette's Products**

Roquette has supplemented its response to Interrogatory No. 11. Roquette also has produced five (5) samples of Roquette product that is considered to be covered by the '777 patent.

All that remains in this category is SPI's request for identification of Roquette products, as well as actual samples, that are covered by French Published Patent Application Nos. FR 2,571,045 and FR 2,571,046. Roquette considers its objections as to that remainder to be well-founded.

Both the '045 and '046 French applications were filed in the French Patent Office on October 3, 1984, and published on April 4, 1986 – more than seven years prior to the filing date of the '777 patent's foreign priority application.

The French applications are not within the same patent family as the patent-in-suit, did not stem from a common initial application as the patent-in-suit, and are not related to the patent-in-suit in the context of this case. The sole overlap of the '045 and '046 French applications with U.S. Patent No. 5,573,777 is that they each share one common inventor, namely, Michel Serpelloni, and a common owner – Roquette Freres.

We cannot discern any possible relevance to this case of SPI's request for identification, much less actual samples, of products covered by old, unrelated, foreign published patent applications.

Your only contention of relevance is that the '045 and '046 French published applications are cited in the specification of the patent-in-suit.

Roquette does not contest that SPI is entitled to copies of the '045 and '046 publications cited in the specification of the patent-in-suit. Those published applications are readily publicly available, and we assume that SPI has them.

Your contention that Roquette must consider the prosecution histories of the unrelated French applications relevant, merely because Roquette produced them, is not tenable. Roquette has consistently and repeatedly objected to SPI's numerous discovery requests for information that relates solely to patent publications other than the patent-in-suit. Roquette maintains its stated objections in that respect, including its objection that the '045 and '046 French prosecution histories are not relevant, and not reasonably calculated to lead to the discovery of admissible evidence.

Oren D. Langer
July 20, 2007
Page 3 of 4

Contrary to your inference, Roquette's production of those prosecution histories evidences nothing more than Roquette's willingness to cooperate, in order to avoid needless expense on both parties and waste of the Court's time and resources.

Even if SPI's contention that the French prosecution histories might be relevant were adopted, that bears no relation whatsoever to whether Roquette's products, if any, might be covered by those unrelated French applications. Moreover, Roquette is not obliged to determine which, if any, of its products might be covered by the French applications.

SPI's request for actual samples under those unrelated French applications is even more removed from the issues of this case.

4. **'777 Patent – U.S. and Foreign Prosecution History Files**

Your statement that Roquette indicated that it possessed or controlled non-privileged prosecution files that it was unwilling to produce is incorrect. Roquette made no such indication.

Roquette has produced all of its non-privileged documents relating to the prosecution of the patent-in-suit.

Although Roquette maintains its objections that foreign counterpart patent documents, including their prosecution histories, lack any relevance or relation to this case, Roquette did state during the meet and confer teleconference that, in a spirit of cooperation, Roquette would gather and produce any non-privileged counterpart prosecution histories that are found. Obviously, those documents, if they exist, will exist in distinct and distant locations worldwide. Roquette's efforts to locate any such documents are ongoing.

5. **'777 Patent and Any Secondary Indicia Evidence**

Roquette will produce existing responsive documents, if any.

6. **Privilege Logs**

Roquette concurs that the parties agreed that they will exchange privilege logs at a mutually convenient time after the parties reached agreement as to a suitable cut-off date, such that neither of the parties is needlessly burdened with excessive labor and expense.

SPI stated during the meet and confer teleconference that it wished to consider what it believed to be an appropriate cut-off date, and Roquette awaits SPI's completion of its consideration.

Oren D. Langer
July 20, 2007
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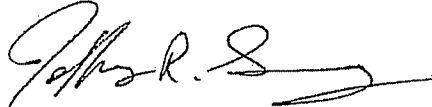
7. Kennet Deposition

At his deposition, Mr. Kennet agreed to produce additional documents. By way of example, and without limitation, Mr. Kennet agreed to produce: documents regarding the name change from Drytec Holdings Limited to Anhydro UK Holdings Limited; all documents responsive to Category 6 of the Schedule A attachment to the deposition notice; :

REDACTED

Please let us know when we may expect to receive the documents identified during Mr. Kennet's deposition.

Sincerely,

A handwritten signature in black ink, appearing to read "Jeffrey R. Snay", with a long horizontal flourish extending to the right.

Jeffrey R. Snay